MICHBIO Statement to the House Judiciary Committee on the Proposed Repeal of Michigan's Tort Reform Laws.

Stephen Rapundalo, Ph.D.
President & CEO, MichBio

March 18, 2009

Good morning. I'm Dr. Stephen Rapundalo, President & CEO of MichBio, the statewide biosciences industry association - home to over 550 bioscience companies, institutions and organizations. They reflect a varied set of industry sub-sectors like pharmaceuticals and therapeutics, medical devices and equipment, diagnostics, research products and tools, informatics, clinical research, bio-agriculture, bio-environmental, bio-defense, and industrial biotechnology. MichBio represents over 230 bioscience R&D and specialized services companies, academic and clinical research institutions, and related bioscience organizations, both public and private. Our members include big small, from Perrigo, Pfizer, Caraco Pharmaceuticals, Dow, Kellogg, Johnson & Johnson, Terumo and MPI Research, to InRad, Asterand, MedBio, Oxford Biomedical, Assay Designs, Housey Pharmaceuticals, and Lumigen, as well as the Van Andel, Borgess, U-M Life Sciences and Karmanos Institutes, and Beaumont, Henry Ford and U-M Hospitals, among many, many others.

The biosciences industry is "big business" in Michigan and accounts for almost 100,000 direct and indirect jobs. This is according to an economic impact study that PhRMA and MichBio released about a month ago. The report, authored by the economist team of Fulton and Grimes at the U-M, clearly demonstrates that the biosciences technology sector has the greatest amount of infrastructure, assets, capabilities and talent, of all the high-tech areas. Private bioscience R&D and academic research in Michigan contributes $9.34 billion to the state's GRP, including $2.5 billion in direct private payroll and $462 million in state tax revenues. The bioscience industry reaches into 82 out of the 83 counties in the state.

While Michigan continues to suffer from losses in the automotive and advanced manufacturing sectors, we have made tremendous strides in diversifying our economy and improving the climate for business growth and investment. For the last 8 years, Michigan has sought to establish its position as a key player in the extremely competitive biosciences industry. The state has invested over $320 million in bioscience companies since 1999, and another $47 million by investing capital into venture funds that in turn have invested in bioscience companies. The biosciences have been an express target for Michigan's "business plan". Placing a big "bulls eye" on this industry by repealing the tort reform laws could not come at a worse time for Michigan – such a step absolutely makes no business and economic sense at all.

Some have questioned the argument that tort reform can be manifested in economic development gains or losses. No doubt such correlations are difficult to make primarily because no data has ever been captured either here or elsewhere that directly addresses that question. All I know is that Michigan has enjoyed good growth in the biosciences over the last eight years with over 120 new companies and new ones wanting to come in – I just received emails from two companies in the last week from out of state interested in coming here. Opponents though would point to the fact that Michigan, despite its tort reform laws has not witnessed an economic boom as demonstrated by the significant downsizing by Pfizer in the last few years, and the fact that the state currently leads the nation with the highest unemployment rate. I would submit to you that the presence or absence of tort reform was not a factor in either of those circumstances. However, the timing of Pfizer's announcements certainly coincided with one of the last introductions of tort reform repeal. And I know from national calls wherein we discuss state legislative affairs, I hear all the time how companies are making business decisions relative to the business and regulatory climates in those states – it's scary at what's being considered and I continually hope that we don't have to suffer that here due to some negative cataclysmic shift in legislation.

Clearly, bioscience companies are inherently high-risk ventures. Approval of the proposed bills and repeal of tort reform would significantly increase the level of risk and potential liability that bioscience companies must contend with. It's all about developing and maintaining a business- and regulatory-friendly environment. The fact is that business decisions are made based on a variety of factors with the litigation climate being one such consideration. Michigan already suffers from the perception of being a high-tax state – the MBT has assured that. We took a positive step forward last November by easing the restrictions on embryonic stem cell research – already the impact of that decision is being felt on the academic research front and even in the industry's commercialization space. Since Michigan's tort reform measure took effect in 1996 the state is viewed as being one of the most favorable from a liability standpoint and where court tort filings have been reduced by over a third. These are precisely the type of business-friendly actions needed to encourage growth in the biosciences sector.

In the absence of hard data, let me share with you an example of what our companies face in their daily business lives. Just yesterday, I had the occasion to visit DCS Products & Laboratories in Muskegon. DCS, with 35 employees, is a contract manufacturer of small-lot and specialty pharmaceutical preparations – liquids, creams, ointments; prescription, over-the-counter, and controlled substances. A few years ago, DCS was sued in California where there are no tort reform laws over a 3rd-party product that they manufactured under contract – DCS simply followed the recipe provided by the client under authorized GMP approval of the FDA. In short, the case was settled upon advice of counsel because it was cheaper to do that than run the risk of a drawn out litigation with no better likelihood of verdict. DCS received no payout on a claim to their insurer and thus had to pay approximately $100,000 out of pocket to cover their portion of the settlement and lawyer fees. That $100,000 was DCS' profit margin for the year. Fortunately, it was but only a single product – can you imagine if they had to contend with multiple such cases and none of them were even their own developed and branded products!

An isolated case? Hardly. This kind of circumstance plays itself out constantly. Tomorrow this could just as easily be Afid Therapeutics in East Lansing, Ferndale Labs in Ferndale, Esperion Therapeutics and Lycera Pharmaceuticals in Northfield Township, Ash Stevens in Riverview, Velcura Therapeutics and Meditrina Pharmaceuticals in Ann Arbor, Perrigo in Allegan, or Vertellas Health & Specialty Products in Zeeland, to name a few other bioscience R&D and contract research companies. Whether emerging or established, large or small, the bottom line is that R&D costs would rise to contend with increased liability risk and bottom lines would be impacted, some to the point that could necessitate a very early, unplanned and devastating exit strategy. This isn't just about "big pharma", it's really about the small to mid-sized companies in your very own districts.

Of greater concern to the bioscience companies is that the proposed bills would revive claims previously barred. The immediate effect of eliminating this tort reform would be to dump a huge backlog of new cases into the tort system – a proverbial opening of the floodgates. Ironically, the inevitable barrage of trial lawyer advertising to net this mass of potential clients could likely identify even more claims than otherwise would have been filed had tort reform never been enacted. Indeed, the TV ads by trial lawyers would likely even outnumber the direct-to-patient educational spots for approved drugs. The potential devastating impact would go even further beyond the bioscience industry as healthcare providers, wholesalers, retailers, and others in supply-to-patient chain are added to the drug product cases. We need to keep the courts free to pursue justice in cases with merit, protect existing businesses and insure their focus is on the science.

Drugs are uniquely "unavoidably unsafe" and it is known that they will harm some users, both foreseeable and not. There's not a vitamin, aspirin or prescription drug that doesn't have some sort of side effects, to one degree of severity or another, in every individual. What works for you, won't work for me, or perhaps not to the same extent. However, the benefits to those for whom a drug is indicated far outweigh the risks to

that class of users. This is the basis upon which the FDA makes a determination of risk/benefit with the expert input opinion of independent peer-reviewers. Having been a NIH and American Heart Association peer reviewer myself and dealt with enormous amounts of scientific and technical information per case, I find it unfathomable how a lay jury with no medical or science training could somehow be in a better position to judge the merits of drug product case in a short time span as compared to the many experts who pour over rooms full of information for 12-18 months before rendering a decision on a product's fate. The fact is that no one can reach a better conclusion than the FDA on a drug safety or labeling matter, and I say that even acknowledging that the agency is overworked, understaffed and underfunded.

Make no mistake – the FDA is the final arbiter in drug approval and manufacturing, despite what the Supreme Court's recent decision may imply. When all is said and done, it is the FDA that regulates and inspects facilities. It alone has the power to modify, shut down and enforce arbitrarily and without caution to business viability. For instance, DCS Labs in Muskegon began investing and greatly expanding their facility based on the success of a single product line with the real expectation of tripling their business with a class of related products. The FDA came in without warning and forced a shut down of the product line due to some apparent safety issues unrelated to DCS. So not only did they lose their potential new business but lost their existing product line, for a net loss. It seems that even if you play by the rules, you lose. And they're not alone. Ask Caraco Pharmaceuticals in Detroit, Stryker in Kalamazoo, or Xoran Technologies and Adeona Pharmaceuticals in Ann Arbor, about the FDA, and listen to their responses. When the FDA calls, you listen and fast, your livelihood depends on it.

Tort reform repeal leading to increased litigation will also impact healthcare delivery. Prescribing habits by doctors are altered when they're aware that a certain drug was/is involved in product liability litigation, irrespective of whether the product was ultimately reaffirmed to be safe. Worse is that patient compliance drops when they learn of

product liability litigation involving a drug that was properly prescribed for them. And we wonder why we can't get a better handle on healthcare costs these days?

Furthermore, the consumer assumes risk too when the uncertainty inherent with every drug is returned to the manufacturer or seller. We trade the risk of potential adverse outcomes by a relative micro-population for the risk of drug availability or lack of affordability. The others in the supply chain too incur the added costs of risk, and guess who gets to pay off on those – the patient/consumer of course. And so goes the debate on healthcare reform.

So let's leave product liability to the experts, and the tort system as is. Current law and process present an appropriate balance whereby the FDA is allowed to perform its regulatory duties, but allowing for punishment of companies that willfully withhold information or interfere with the drug approval process. Let's not unduly raise the risks for the many due to failures of the few, where current law and tort reform already provides for meaningful recourse to the injured.

Most importantly, the passage of the proposed bills will have significant repercussions on the bioscience and healthcare industry, and Michigan citizens if enacted. Let's not forsake many years of investment and effort in bolstering and growing the biosciences industry to only see it vanish by creating a business environment that unduly burdens our companies with greater liability. We need the legislature's help in sustaining our industry not breaking it. On behalf of the state's bioscience companies, institutions and organizations I would strongly urge you to oppose repeal of tort reform legislation.